S/N 10/657,820 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Ashok V. Joshi	Examiner: Darwin P. Erezo
Serial No.:	10/657,820	Group Art Unit: 3731
Filed:	September 8, 2003	Docket No.: MIC 031103
Title:	DEVICE AND METHOD FOR WOUND THERAPY	

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

This paper is filed in response to the Final Office Action mailed on June 29, 2006. Applicant expresses appreciation for the telephonic interview with Examiner on August 18, 2006. Please amend the above-identified patent application as follows:

Amendments to the Claims begin on Page 2.

Remarks begin on Page 14.

IN THE CLAIMS

Please amend the claims as follows:

Claim 1 (withdrawn): A disposable wound-therapy device comprising:

a fluid impermeable housing having a cavity therein, wherein the cavity includes at least one opening adapted to encompass at least a portion of a wound region of a patient;

a perimeter surrounding the at least one opening;

means for sealing the perimeter to a surface of the patient proximate the wound region; and

means for at least one of absorbing and removing oxygen from within the cavity integrated into the housing.

Claim 2 (withdrawn): The wound-therapy device according to Claim 1, wherein the absorbing means is placed within the cavity.

Claim 3 (withdrawn): The wound-therapy device according to Claim 1, wherein the absorbing means comprises a chemical absorber.

Claim 4 (withdrawn): The wound-therapy device according to Claim 3, wherein the chemical absorber is selected from the group consisting of metal powders, activated carbon, catalyst material, zeolites and mixtures and combinations thereof.

Claim 5 (withdrawn): The wound-therapy device according to Claim 1, wherein the absorbing means comprises at least one electrochemical cell.

Claim 6 (withdrawn): The wound-therapy device according to Claim 5, wherein the electrochemical cell comprises a metal/air cell.

Claim 7 (withdrawn): The wound-therapy device according to Claim 6, wherein the metal/air cell comprises one of the group consisting of a zinc/air cell, a magnesium/air cell, an aluminum/air cell, and an iron/air cell.

Claim 8 (withdrawn): The wound-therapy device according to Claim 5, wherein the electrochemical cell comprises a nafion-based cell.

Claim 9 (withdrawn): The wound-therapy device according to Claim 1, additionally comprising means for absorbing fluid associated with the cavity.

Claim 10 (withdrawn): The wound-therapy device according to Claim 9, wherein the fluid-absorbing means comprises an antimicrobial material.

Claim 11 (withdrawn): The wound-therapy device according to Claim 10, wherein the antimicrobial materials comprise one or more materials selected from the group consisting of silver compounds, halide compounds, peroxides, super oxides, and organic disinfectants.

Claim 12 (withdrawn): The wound-therapy device according to Claim 9, wherein the fluid-absorbing means comprises a porous material.

Claim 13 (withdrawn): The wound-therapy device according to Claim 12, wherein the porous material comprises an adhesive mesh.

Claim 14 (withdrawn): The wound-therapy device according to Claim 1, wherein the housing comprises one or more materials selected from the group consisting of steel, aluminum, copper alloys, and dense plastics.

Claim 15 (withdrawn): The wound-therapy device according to Claim 14, wherein the dense plastics comprise materials selected from the group consisting of polypropylene, polyvinyl chlorides, polyethylene, berex, nylon, and Teflon.

Claim 16 (withdrawn): The wound-therapy device according to Claim 1, further comprising a valve associated with the housing, wherein the valve comprises means for introducing additional oxygen into the cavity.

Claim 17 (currently amended): A disposable wound-therapy device comprising:

- a fluid-impermeable housing having a cavity therein, wherein the cavity includes at least one opening adapted to encompass at least a portion of a wound region of a patient, and a chamber for receiving a fluid;
- a perimeter surrounding the at least one opening;
- means for sealing the perimeter to a surface of the patient proximate the wound region; and
- a porous sponge associated with the cavity, wherein the sponge is capable of retaining a fluid therein; and
- an osmotic cell, having an osmotic membrane, positioned between the cavity and the chamber, for removing the fluid from the sponge, and transporting it into the chamber.

Claim 18 (previously presented): The wound-therapy device according to Claim 17, wherein the osmotic cell is integrated into the housing.

Claim 19 (original): The wound-therapy device according to Claim 17, wherein the porous sponge comprises an antimicrobial material.

Claim 20 (previously presented): The wound-therapy device according to Claim 17, wherein the porous sponge is configured to be at least partially impregnated with a fluid immediately prior to use.

Claim 21 (previously presented): The wound-therapy device according to Claim 20, wherein the porous sponge comprises an antimicrobial fluid.

Claim 22 (previously presented): The wound-therapy device according to Claim 17, wherein the chamber is adjacent the cavity, wherein the osmotic cell removes a fluid from the porous sponge into the chamber.

Claim 23 (original): The wound-therapy device according to Claim 17, wherein the porous sponge is at least partially within the cavity.

Claim 24 (withdrawn): The wound-therapy device according to Claim 17, wherein the removing means comprises a super-polymer absorber.

Claim 25 (withdrawn): The wound-therapy device according to Claim 24, wherein the super-polymer absorber is one or more crystals selected from the group consisting of sodium polyacrylate and polyacrylamide.

Claim 26 (currently amended): The wound-therapy device according to Claim 17, wherein the osmotic ~~cell comprises an osmotic~~ membrane is in fluidic communication with the porous sponge.

Claim 27 (previously presented): The wound-therapy device according to Claim 17, wherein the osmotic cell comprises an electro-osmotic cell, the electro-osmotic cell comprising an anode and a cathode.

Claim 28 (previously presented): The wound-therapy device according to Claim 17, wherein the osmotic cell comprises an electro-osmotic cell, the electro-osmotic cell comprising a cationic membrane.

Claim 29 (previously presented): The wound-therapy device according to Claim 17, wherein the osmotic cell comprises an electro-osmotic cell, the electro-osmotic cell comprising an anionic membrane.

Claim 30 (withdrawn): The wound-therapy device according to Claim 17, wherein the housing comprises a material that is resiliently deformable upon application of a pressure.

Claim 31 (withdrawn): The wound-therapy device according to Claim 30, wherein the removing means comprises depressing a portion of the resiliently deformable housing to, in turn, create a negative pressure over the wound.

Claim 32 (withdrawn): The wound-therapy device according to Claim 17, wherein the removing means comprises a syringe associated with the housing, which may withdraw any fluid retained within the sponge.

Claim 33 (withdrawn): The wound-therapy device according to Claim 30, the housing having a fluid-retention chamber adjacent the porous sponge, wherein the removing means comprises a one-way valve between the porous sponge and the fluid-retention chamber such that, upon application of pressure, fluid is removed from the sponge and into the fluid-retention chamber.

Claim 34 (currently amended): A disposable wound-therapy device comprising:

- a fluid impermeable housing having a cavity therein and a retention chamber, wherein the cavity includes a sponge and at least one opening adapted to encompass at least a portion of a wound region of a patient;
- a perimeter substantially surrounding the at least one opening;
- ~~means for sealing the perimeter to a surface of the patient proximate the wound region;~~ and
- an osmotic cell, having an osmotic membrane, positioned between the chamber and the cavity, for removing fluid from within the cavity, and transporting it into the retention chamber.

Claim 35 (previously presented): The device according to Claim 34, wherein the osmotic cell continuously removes the fluid from within the wound region.

Claim 36 (previously presented): The device according to Claim 34, wherein the osmotic cell is integrated into the housing.

Claim 37 (currently amended): The device according to Claim 34, ~~wherein the fluid removing means~~ further ~~comprises~~ comprising at least one capillary tube to facilitate removal of fluid from the cavity.

Claim 38 (currently amended): The device according to Claim 34, ~~wherein the fluid removing means comprises~~ further comprising an absorbent polymer to facilitate removal of fluid from the cavity.

Claim 39 (previously presented): The device according to Claim 34, wherein the retention chamber is external to the cavity, and associated with the osmotic cell, such that fluid removed from the cavity is delivered to the retention chamber.

Claim 40 (previously presented): The device according to Claim 34, wherein the retention chamber additionally comprises means for absorbing and retaining fluid.

Claim 41 (original): The device according to Claim 40, wherein the absorbing and retaining means comprises a porous matrix.

Claim 42 (withdrawn): The wound-therapy device according to Claim 34, wherein the housing comprises a material that is resiliently deformable upon application of a pressure.

Claim 43 (withdrawn): The wound-therapy device according to Claim 39, wherein the removing means comprises depressing a portion of the resiliently deformable housing to, in turn, create a negative pressure over the wound.

Claim 44 (withdrawn): The wound-therapy device according to Claim 34, wherein the removing means comprises a syringe associated with the housing, which may withdraw any fluid retained within the sponge.

Claim 45 (withdrawn): A device for promoting healing of a wound region, comprising:

at least one device capable of exerting an approximately downward pressure on at least two tissue regions of a patient surrounding the wound region, wherein the at least two tissue regions are located distally from each other across the wound region; and

means for maintaining the exerted pressure for one or more hours.

Claim 46 (withdrawn): The device according to Claim 45, wherein the at least one device comprises at least two pressure bands, which bands may be placed around an appendage and proximate the wound region, wherein the exerted pressure maintaining means comprises constructing the pressure bands from a resiliently elastic material.

Claim 47 (withdrawn): The device according to Claim 45, wherein the wound region includes an open wound area and a perimeter surrounding the open wound area, and the device includes means for substantially closing the open wound area by forcing at least a first region of the perimeter towards a second region of the perimeter.

Claim 48 (withdrawn): The device according to Claim 47, wherein the closing means comprises means for connecting the at least two pressure bands together.

Claim 49 (withdrawn): The device according to Claim 47, wherein the closing means comprises an adhesive strip capable of bridging across the open wound area.

Claim 50 (withdrawn): A method of promoting healing of a wound region, comprising the steps of:

placing a device capable of exerting an approximately downward pressure on at least two tissue regions of a patient surrounding the wound region; and

exerting a downward pressure on the at least two tissue regions using the device, to, in turn, substantially close the wound region.

Claim 51 (withdrawn): The method according to Claim 50, further comprising the step of associating an absorbent material with the wound region to, in turn, removing wound fluid from within the wound region.

Claim 52 (withdrawn): The device according to Claim 17, wherein the osmotic cell further comprises a salt.

Claim 53 (withdrawn): The device according to Claim 52, wherein the salt is a salt solution.

Claim 54 (withdrawn): The device according to Claim 52, wherein the salt is a salt tablet.

Claim 55 (previously presented): The device according to Claim 27, wherein the electro-osmotic cell further comprises an activation switch.

Claim 56 (withdrawn): The device according to Claim 17, further comprising a water injection means.

Claim 57 (withdrawn): The device according to Claim 34, wherein the osmotic cell further comprises a salt.

Claim 58 (withdrawn): The device according to Claim 56, wherein the salt is a salt solution.

Claim 59 (withdrawn): The device according to Claim 56, wherein the salt is a salt tablet.

Claim 60 (previously presented): The device according to Claim 34, wherein the osmotic cell comprises an electro-osmotic cell, the electro-osmotic cell comprising an anode and a cathode.

Claim 61 (previously presented): The device according to Claim 34, wherein the osmotic cell comprises an electro-osmotic cell, the electro-osmotic cell comprising a cationic membrane.

Claim 62 (previously presented): The device according to Claim 34, wherein the osmotic cell comprises an electro-osmotic cell, the electro-osmotic cell comprising an anionic membrane.

Claim 63 (previously presented): The device according to Claim 60, wherein the electro-osmotic cell further comprises an activation switch.

Claim 64 (withdrawn): The device according to Claim 34, further comprising a water injection means.

REMARKS

In the Office Action, claims 1-64 are pending in the application. Claims 1-16, 24, 25, 30-33, 37, 38, 42-54, 56-59, and 64 are withdrawn from consideration. Claims 17-23, 26, 34-36, 40 and 41 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No.: 5,167,613, to Karami, *et al.* (hereinafter "Karami"). Claims 27-29, 55 and 60-63 were rejected under 35 U.S.C. §103(a) as being unpatentable over Karami in view of U.S. Patent Publication No.: US 2003/0050594 to Zamierowski (hereinafter "Zamierowski"). Claim 39 was deemed to have allowable subject matter.

Interview Summary

Applicant wishes to thank Examiner Erezo for the telephonic interview conducted on August 18, 2006. During the interview, the Karami reference was discussed and a claim amendment was proposed to would overcome the §102 and §103 rejections since Karami fails to teach an osmotic membrane. The amendments to claims 17 and 34 proposed in the interview are presented formally in this paper. By this paper, claims 17, 26, 34, 37, and 38 have been amended.

§102 Rejection of the Claims

Claims 17-23, 26, 34-36, 40 and 41were rejected under 35 U.S.C. §102(b) as being anticipated by Karami. For a reference to anticipate a claim under 35 U.S.C. §102(b), "each and every element as set forth in the claim [must be] found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631 (Fed. Cir. 1987), cited in MPEP §2131. As proposed in the interview, claims 17 and 34 are hereby amended to state that the osmotic cell includes an osmotic membrane positioned between the chamber and cavity. This amendment is well-supported in the specification which references osmotic cells having osmotic membranes. Karami does not teach or even mention an osmotic cell and does not teach the recognized components of an osmotic cell, including an osmotic membrane. As a result, Karami fails to teach each and every limitation of the independent claims. Thus, Applicant respectfully requests that this rejection be withdrawn.

§103 Rejections of the Claims

Claims 27-29, 55 and 60-63 were rejected under 35 U.S.C. §103(a) as being unpatentable over Karami in view of U.S. Patent Publication No.: US 2003/0050594 to Zamierowski (hereinafter "Zamierowski"). As with 35 U.S.C. §102 rejections, rejections under 35 U.S.C. §103(a) must teach each and every element of the claims. As amended, as noted above, Karami fails to teach a housing having a chamber and an osmotic cell for removing the fluid from a sponge to the chamber. Zamierowski does not teach an osmotic membrane positioned between the chamber and the cavity.

Additionally, in order for two prior art referenced to be combined in a Section 103 rejection, there must be some motivation to do so. In the present case, there is no motivation to combined Karami and Zamierowski. Karami addresses a localized application dealing with wound healing whereas Zamierowski contemplates monitoring and remote collection, suction sources, and collection sites for found therapy. Zamierowski would not seek to utilize the teachings of Karami, which teaches a localized band aid ® not a therapy system. Likewise, the purpose of Karami is to be free from the hoses required to conduct wound therapy under Zamierowski.

The mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990) (Claims were directed to an apparatus for producing an aerated cementitious composition by drawing air into the cementitious composition by driving the output pump at a capacity greater than the feed rate. The prior art reference taught that the feed means can be run at a variable speed, however the court found that this does not require that the output pump be run at the claimed speed so that air is drawn into the mixing

chamber and is entrained in the ingredients during operation. Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." 916 F.2d at 682, 16 USPQ2d at 1432.). See also *In re Fritch*, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992) (flexible landscape edging device which is conformable to a ground surface of varying slope not suggested by combination of prior art references).

Additionally, if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). Karami and Zamierowski both reference wounds. But that is the extent of their similarities. There would be no motivation to modify either invention to create the other invention. Karami is meant to be a disposable, untethered, and less expensive dressing to keep the wound dry. Adding the teachings of Zamierowski to Karami would totally defeat the purpose of Karami. Similarly, by removing the hosing, monitoring capabilities, and assemblies of Zamierowski, you could conceivably get to Karami, however, you would lose the ability to conduct therapy, which is the purpose of Zamierowski. Accordingly, it would not be obvious to combine Karami and Zamierowski and Applicant respectfully requests withdrawal of Examiner's Section 103 rejection.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (801-978-2186) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 50-3586

Respectfully submitted,

ASHOK V. JOSHI

By his Representative,

Date 8/29/2006

By _____
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